PATENT

Attorney Docket No.: 08321-0113US1



N THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:

Patent application of

Jay S. Schneider

Group Art Unit:

Serial No.

10/660,090

1614

Filing Date:

September 11, 2003

Examiner:

Phyllis G. Spivack

For:

METHODS AND KIT FOR TREATING

PARKINSON'S DISEASE

:

DECLARATION UNDER 37 C.F.R. 1.132

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

It is declared that:

- 1. I, Jay S. Schneider, Ph.D., am the inventor named in the above-identified patent application.
- 2. Attached is Exhibit A (Figure 1) which describes the results of three separate sets of experiments that I performed in order to study the effects of ACPC on (Fig. 1A) dyskinesia, (Fig. 1B) dystonia and (Fig. 1C) levodopa (L-Dopa) peak efficiency. Three

CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.8(a)

I hereby certify that this paper, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date indicated below, with sufficient postage, as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Box 1430, Alexandria, VA 22313-1430

DATE: March 15, 200 6

(Fig. 1B) dystonia and (Fig. 1C) levodopa (L-Dopa) peak efficiency. Three hundred sixty mg/kg ACPC was administered to a parkinsonian adult cynomolgus monkey with an established therapeutic response to L-Dopa, together with 45 mg/kg of L-Dopa and 50 mg/kg of the 63/11 peripheral dopa decarboxylase inhibitor benserazide. Each experiment was performed in triplicate and the symptomatic benefit was assessed by raters blind to treatment conditions. The results in Figure 1A show that treatment with ACPC decreased the severity and frequency of the dyskinesia by approximately 30% although ACPC did not have an effect on dystonia or the peak dose efficiency of L-Dopa (Figures 1B and 1C).

I hereby declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

03/14/06 Date